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February 6, 2008

The Honorable Gregory M. Sleet
United States District Court
For the District of Delaware
844 North King Street
Wilmington, DE 19801


VIA ELECTRONIC FILING

Re: *Santarus, Inc. et al. v. Par Pharmaceutical, Inc.*
C.A. No. 07-551 (GMS)

Dear Chief Judge Sleet:

Attached is the parties' Joint Status Report, for discussion during the conference on Monday afternoon.

Respectfully,



Jack B. Blumenfeld

JBB/nlm
Enclosure

cc: Clerk of Court (Via Hand Delivery; w/ encl.)
Frederick L. Cottrell, Esq. (Via E-mail; w/encl.)
Daniel G. Brown, Esq. (Via E-mail; w/encl.)
Gary N. Frischling, Esq. (Via E-mail; w/encl.)
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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANTARUS, INC., a Delaware corporation,)	
and THE CURATORS OF THE)	
UNIVERSITY OF MISSOURI, a public)	
corporation and body politic of the State of)	
Missouri,)	
)	C.A. No. 07-551-GMS
Plaintiffs,)	
)	
v.)	
)	
PAR PHARMACEUTICAL, INC., a Delaware)	
corporation,)	
)	
Defendant.)	

JOINT STATUS REPORT

Pursuant to Rule 16 of the Federal Rules of Civil Procedure, D. Del. L.R. 16.2(b), and the Court's January 31, 2008 Order (D.I. 13), the parties, by and through their undersigned counsel, jointly submit this Status Report. Counsel for the parties conferred in preparation for the status and scheduling conference before the Court on February 5, 2008 at 11:30 a.m. Attached for the Court's consideration as Exhibit A is a chart summarizing the parties' proposed schedule for this action.

1. Substance of the Action

This is a Hatch-Waxman Act patent infringement action. Plaintiff Santarus, Inc. ("Santarus") sells a drug product in the form of 20 mg omeprazole/ sodium bicarbonate capsules, and 40 mg omeprazole/sodium bicarbonate capsules, both under the trademark ZEGERID®.

Plaintiffs contend that these capsules are covered by United States Patent Nos. 6,645,988 (the "'988 patent"); 6,489,346 (the "'346 patent"); and 6,699,885 (the "'885 patent'). Plaintiffs assert that the '988 patent, the '346 patent and the '885 patent are owned by The Curators of the University of Missouri and are exclusively licensed to Santarus. These drug capsules are

indicated for the treatment of heartburn and other symptoms of gastroesophageal reflux disease, the maintenance of healing of erosive esophagitis, and the short-term treatment of active duodenal ulcers and active benign gastric ulcers.

Defendant Par Pharmaceutical, Inc., (“Par”) filed an Abbreviated New Drug Application (“ANDA”) No. 78-966 with the FDA seeking approval for generic 20 mg omeprazole/sodium bicarbonate capsules, and 40 mg omeprazole/sodium bicarbonate capsules, (“the ANDA Capsule Products”) before the July 16, 2016 expiration of the ‘988, ‘346 and ‘885 patents.

Plaintiffs filed this action (the “First Action”) alleging that the submission of Defendant’s ANDA was an act of infringement of the ‘988, ‘346, and ‘885 patents under 35 U.S.C. § 271(e)(2). Defendant denies infringement, and contends that the claims of the ‘988, ‘346 and ‘885 patents are invalid and unenforceable due to inequitable conduct.

On December 20, 2007, Plaintiffs filed a second patent infringement lawsuit against Par for infringement of the patents listed in the Orange Book for Zegerid[®] Powder for Oral Suspension. That case has also been assigned to this Court as Civil Action No. 07-827-GMS (the “Second Action”). The Second Action is in response to a second ANDA (No. 79-182) filed by Par with the FDA regarding Par’s request for approval of generic omeprazole/sodium bicarbonate powder for oral suspension (“the ANDA Powder Products”). In the Second Action, Plaintiffs asserted four patents, the ‘988, ‘346 and ‘885 patents asserted in the First Action, along with U.S. Patent No. 6,780,882 (the “‘882 patent”). A fifth patent, U.S. Patent No. 5,840,737 (the “‘737 patent”) is listed in the Orange Book for the Powder Products but was not asserted by Plaintiffs. On December 20, 2007, The Curators of the University of Missouri filed an application with the PTO seeking reissue of the ‘737 patent and amendment of its claims. That application currently is pending.

On January 30, 2008, Par filed an Amended Answer and Counterclaims, generally denying infringement and alleging invalidity and unenforceability and seeking a declaratory judgment of non-infringement, invalidity and unenforceability of all four asserted patents plus the ‘737 patent. Plaintiffs expect to file a reply to the Counterclaims shortly.

The parties agree that the First Action and the Second Action should be consolidated for all purposes.

2. Jurisdiction and Service

The parties agree that the Court has subject-matter jurisdiction over Plaintiffs' claims and Defendant's counterclaims in the First Action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. The parties further agree that the Court has personal jurisdiction over the parties for purposes of this action and venue is proper.

As for the Second Action, the parties agree that the Court has subject-matter jurisdiction over Plaintiffs' claims. With respect to Defendant's declaratory judgment counterclaims in the Second Action, Plaintiff believes that subject matter jurisdiction is lacking with respect to the '737 patent because Plaintiff did not assert that patent against Defendants and the '737 patent is undergoing reissue proceedings seeking amendment of its claims. Plaintiffs plan to file a motion to dismiss the declaratory judgment claim as to '737 patent, or in the alternative, to stay the declaratory judgment claim as to the '737 patent until after the reissue proceeding in the Patent Office has concluded. Defendant believes that subject matter jurisdiction over its declaratory judgment claims relating to the '737 patent is proper under recent Federal Circuit caselaw. The parties further agree that the Court has personal jurisdiction over the parties for purposes of this action and venue is proper.

3. Identification of Issues

(A) Plaintiffs

Whether Defendant's submission of the ANDAs was an act of infringement of the patents-in-suit under 35 U.S.C. § 271(e)(2) because the commercial manufacture, use, offer for sale, or sale of the ANDA Capsule and Powder Products would infringe one or more claims of the patents-in-suit.

(B) Defendant

Whether the ANDA Capsule and Powder Products do not infringe the ‘988, ‘346, ‘885, ‘882, and ‘737 patents; whether the ‘988, ‘346, ‘885, ‘882, and ‘737 patents are invalid, including over the prior art and/or public uses by the inventor; and whether the ‘988, ‘346, ‘885, ‘882, and ‘737 patents are unenforceable due to inequitable conduct, including for failure to disclose to the Patent Office material information relating to public uses by the inventor.

4. Narrowing of Issues

The parties expect that, as discovery proceeds and the case progresses, they may be able to narrow the issues by way of stipulation or agreement. At this time, other than the anticipated motion by Plaintiffs to dismiss the ‘737 patent from the case, there are no dispositive or partially dispositive issues appropriate for decision or motion.

5. Relief

(A) Plaintiffs

Plaintiffs seek at least the following relief:

1. A determination that Defendant has infringed the ‘346 patent, the ‘885 patent, the ‘882 patent, and the ‘988 patent;
2. A determination that the commercial use, sale, offer for sale, manufacture, and/or importation by Defendant of the ANDA Capsule and Powder Products would infringe the ‘346 patent, the ‘885 patent, the ‘988 patent and, with respect to the Powder Products, the ‘882 patent;
3. A determination, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date for approval of the ANDAs, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), be no earlier than the expiration date of the ‘346 patent, the ‘885 patent, the ‘988

patent, and, with respect to the Powder Products, the '882 patent, including any applicable patent or regulatory extensions;

4. An order preliminarily and permanently enjoining Defendant and its affiliates, subsidiaries, officers, directors, employees, agents, representatives, licensees, successors, assigns, and all those acting for them and on their behalf, or acting in concert with them directly or indirectly, from infringing the '346 patent, the '885 patent, the '882 patent, and the '988 patent; and

5. A declaration that this case is exceptional pursuant to 35 U.S.C. § 285 and an award of attorneys' fees and costs.

(B) Defendant

Defendant seeks at least the following relief:

1. A declaration that the '988, '346, '885, '882, and '737 patents and all of the respective claims are: (i) not infringed by the ANDA capsule and Powder Products; (ii) invalid; and (iii) unenforceable due to inequitable conduct.

2. A declaration that this case is exceptional pursuant to 35 U.S.C. § 285 and an award of attorneys' fees and costs.

6. Amendment of Pleadings

The parties propose a March 30, 2008 deadline for amendment of pleadings.

7. Joinder of Parties

At present, the parties are not aware of any additional parties who should be joined in this action. The parties propose a March 30, 2008 deadline to add such parties.

8. Discovery

(A) Issues

1. Plaintiffs

Plaintiffs require, at a minimum, the following discovery to prepare for trial: (i) written discovery to, and responses and documents from, Defendant relating to the parties' contentions; (ii) fact depositions of Defendant and its key employees relating to Defendant's alleged infringement; (iii) fact depositions relating to validity issues, including the scope and content of the prior art being asserted by the Defendant and objective evidence of nonobviousness; (iv) discovery relating to Defendant's contentions in this case, including Defendant's contention of inequitable conduct; and (v) expert discovery.

2. Defendant

Defendant requires, at a minimum, the following discovery to prepare for trial: (i) written discovery to, and responses and documents from, Plaintiffs relating to the parties' contentions; (ii) fact depositions of Plaintiffs; attorneys that prosecuted the '988, '346, '885, '882, and '737 patents; and third parties, including relating to Plaintiffs' allegations of infringement; validity issues, including public uses by the inventor; and enforceability issues; (iii) discovery relating to Plaintiffs' contentions in this case; and (iv) expert discovery.

(B) Limitations on Discovery

The parties agree that discovery should be conducted in accordance with the parameters set forth in the Federal Rules of Civil Procedure and the Local Rules of this Court.

The parties agree to limit the number of interrogatories to 25 per side. The parties do not believe that any limitations are required at this time for document requests or requests for admission, as the parties have agreed to be reasonable and cooperative with respect to the number and timing of such requests.

Plaintiffs propose that each side be limited to 10 fact depositions, which number does not include depositions of experts. Plaintiffs believe there is no reason to deviate from the limit set by Fed. R. Civ. P. 30 of 10 depositions. Defendant proposes 150 hours for each side as Defendant believes there may be several as yet unidentified fact witnesses in view of the over 200 patent claims at issue, complex regulatory issues relating to Santarus' Zegerid® products, and Defendant's allegations of public uses by the inventor and of inequitable conduct.

(C) Protective Order

The parties anticipate the need for entry of a protective order to protect the confidentiality of sensitive business information that may be exchanged during discovery, and are in the process of preparing a proposed protective order for this case. The parties anticipate submitting a proposed protective order to the Court for its consideration.

9. Estimated Trial Length

The parties believe at this time that they will require five (5) days to resolve the issues set forth in the parties' respective pleadings. The parties will cooperate in an attempt to reduce the length of trial through the use of stipulations and other means for expediting the presentation of evidence.

10. Jury Trial

The parties agree that because no money damages are being sought, there will be no jury trial.

11. Settlement

The parties have not yet had an opportunity to discuss settlement. The parties are open to referral to a Magistrate Judge for informal mediation or settlement discussion at an appropriate time.

MORRIS, NICHOLS, ARSHT & TUNNELL
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EXHIBIT A

Exhibit A**PROPOSED CASE SCHEDULE****Discovery Period**

Event	Joint Proposal
Initial Disclosures	15 days following entry of scheduling order
Joinder of Other Parties and Amend Pleadings	March 30, 2008
Substantial Completion of Document Production	July 11, 2008
Close of Fact Discovery	November 14, 2008
Opening Expert Reports by Party with Burden of Proof	December 15, 2008
Responsive Expert Reports	January 23, 2009
Rebuttal Expert Reports	February 27, 2009
Close of Expert Discovery	March 31, 2009

Claim Construction

Event	Joint Proposal
Opening Markman Briefs	60 days before hearing date
Responsive Markman Briefs	30 days before hearing date
Markman Hearing	September 2008 proposed; date to be determined by Court

Dispositive Motions

Event	Plaintiffs' Proposal	Defendant's Proposal
Deadline to File Letter Brief Indicating Intent to file MSJ	Plaintiffs believe dispositive motions are unnecessary in this case to be tried to the bench	11/3/2008
Responsive Letter Brief Regarding Filing of MSJ		11/10/2008
Reply Letter Brief Regarding Filing of MSJ		11/14/2008
Status Conference to Determine Whether MSJ Will be Allowed		~12/1/2008
Deadline to File Case Dispositive Motions if Allowed		1/16/2009

Pretrial

Event	Joint Proposal
Parties Exchange respective portions of Pretrial Order	April 30, 2009
Parties Exchange Objections to Other Side's Pretrial Order Submission	May 22, 2009
Motions in limine (fully briefed)	May 26, 2009
Pretrial Order Submitted to Court	May 29, 2009
Pretrial Conference	June/July 2009 proposed; date to be determined by the Court
Trial	August 2009 proposed; date to be determined by the Court